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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,136	07/21/2006	Rebecca Louise Charles nee Newsham	T3109(C)	3175
201 7590 11/25/2009 UNILEVER PATENT GROUP 800 SYLVAN AVENUE AG West S. Wing ENGLEWOOD CLIFFS, NJ 07632-3100				
EXAMINER FLOOD, MICHELE C				
ART UNIT		PAPER NUMBER		
1655				
NOTIFICATION DATE		DELIVERY MODE		
11/25/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentgroupus@unilever.com

Office Action Summary

Application No.

10/587,136

Applicant(s)

CHARLES NEE NEWSHAM ET AL.

Examiner

MICHELE FLOOD

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2009.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8, 17 and 18 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 8, 17 and 18 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on July 9, 2009 with the cancellation of Claims 9, 10 and 26; and the addition of newly added Claim 18.

The indicated allowability of Claim 8, per the incorporation of the limitations of cancelled Claim 16, is withdrawn in view of the newly discovered references to Shrikhande et al. (B**) and Takagaki et al. (O). Rejections based on the newly cited references follow.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 8, 17, and 18 are under consideration.

Response to Arguments

Claim Rejections - 35 USC § 112

Claims 8 and 17, as amended; and newly submitted Claim 18, remain/is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied as necessitated by amendment.

The metes and bound of Claim 8 are rendered vague and indefinite by the phrase, "and wherein the flavanoid comprises a mixture of proanthocyanidins and anthocyanidins", because the method as claimed requires the administration of an effective amount of "(a) a flavanoid" versus a flavanoid wherein the flavanoid is mixture

of proanthocyanidins and anthocyanidins. This rejection is based on the fact that flavanoids are polyphenolic compounds which can be grouped into several classes which include proanthocyanidins and anthocyanidins; and, therefore, "a flavanoid" can be either a proanthocyanidin or an anthocyanidin or a flavanone, but not a mixture of both compounds simultaneously. Perhaps, Applicant intends to direct the claimed subject matter to the administration of a composition containing a flavanoid-containing composition comprising a mixture of proanthocyanidins and anthocyanidins. However, the lack of clarity renders the claim very confusing and ambiguous. For all of the reasons set herein, Claim 17 is similarly rejected as set forth immediately below.

The metes and bound of Claim 17 are rendered vague and indefinite by the phrase, "wherein the flavanoid further comprises one or more flavanones", for all of the reasons set forth immediately above which apply to Claim 8 because it is uncertain as to how a flavanoid which is a mixture of proanthocyanidins and anthocyanidins also is a flavanoid which "further comprises one or more flavanones". The lack of clarity renders the claim ambiguous.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

Claims 8 and 17, as amended, are rejected under 35 U.S.C. 103(a) as being unpatentable over Perrier et al. (A*) in view of Naito et al. (N); and further in light of Shrikhande et al. (B**). Newly applied.

Applicant claims a method of increasing a ratio of light melanin to dark melanin in the skin of a mammal, the method comprising administering to said mammal an effective amount of (a) a flavanoid, (b) vitamin C and (c) vitamin E wherein at least component (b) is administered systemically and (a) and (c) are administered topically and wherein the flavanoid comprises a mixture of proanthocyanidins and anthocyanidins. Applicant further claims the method according to claim 8 wherein the flavanoid further comprises one or more flavanones.

Perrier teaches a method of increasing a ratio of light melanin to dark melanin in the skin of a mammal comprising topically applying to the skin of a mammal an effective amount of a composition comprising vitamin E acetate; an extract of *Saxifrage* containing proanthocyanidins; an extract of mulberry (*Morus nigra*) containing phenylflavones and derivatives thereof including kuwanones and morusin; an extract of *Scutellaria* (*Scutellaria baicalensis*) containing woogonin (a flavanone), baicalin (a flavanoid) and baicalein (a flavone); and, an extract of fruits of grape (*Vitis vinifera*) extract. See Column 3, line 40 to Column 5, line 46; and, Column 6 line 21 to Column 7, line 18. In Column 4, lines 34-49, Perrier teaches that the grape extract is prepared by macerating the fruits of the grape plant in a mixture of water and alcohol (such as ethanol, *etc.*). The reference is silent to the topical administration of a mixture of

proanthocyanidins and anthocyanidins. However, it is well known in the art of polyphenol chemistry that a mixture of water and alcohol can be used to prepare and extract containing a mixture of proanthocyanidins and anthocyanidins from red grapes (including the seeds and skin of grape fruit or pomace), such as the solvent system used to prepare the fruit extract of grapes taught by Perrier. See Column 5, line 31 to Column 6, line 5 of Shrikhande, for example. Thus, it is deemed that the grape extract used in the method of Perrier inherently comprises a mixture of proanthocyanidins and anthocyanidins, since the solvents used in the preparation of the Perrier' grape extract would intrinsically extract the claim-designated flavanoids. The method taught by Perrier inhibits the formation of unwanted pigmentation by inhibiting tyrosinase. Therefore, the method taught by Perrier is deemed to inherently provide a method of increasing the ratio of light melanin to dark melanin in the skin of a mammal comprising the topical administration of the claim-designated ingredients. See Column 6, line 22 to Column 7, line 18, wherein Perrier demonstrates that the skin-depigmenting effect of the above-mentioned topical composition was due to the inhibition of the formation of melanin by inhibiting tyrosinase activity; and, wherein Perrier likens the tyrosinase activity of the patent composition (71% tyrosinase inhibitory activity at a concentration of 0.1%) to the inhibition of tyrosinase by ascorbic acid (66% tyrosinase inhibitory activity at a concentration of 0.1%). See Figure 1.

The teachings of Perrier are set forth above. While Perrier recognizes vitamin C as a tyrosinase inhibitor useful in methods of skin lightening or methods to reduce excessive skin pigmentation, Perrier also teaches that tyrosinase inhibitors such as

ascorbic acid tend to be unstable in topical cosmetic preparations (due to high water content, significant variations in pH and temperature, and the presence of oxygen and numerous other compounds) wherein their rapid oxidation decreases tyrosinase inhibition and results in the black or brown coloration of cosmetic preparations. See Column 1, line 36 to Column 2, line 67. Thus, Perrier teaches the instantly claimed method except for (b) vitamin C, wherein at least component (b) is administered systemically. However, modification of the method taught by Perrier as disclosed by Applicant to provide the instantly claimed method would have *prima facie* obvious to one of ordinary skill in the art because at the time of the invention Naito taught a composition comprising vitamin C for oral administration for skin whitening and removing stain from skin. At the time the invention was made, one of ordinary skill in the art would have been motivated and would have had a reasonable expectation to add the composition taught by Naito for oral administration to the method taught by Perrier to provide the instantly claimed method of increasing the ratio of light melanin to dark melanin in the skin of a mammal because Naito taught that systemic administration of compositions comprising vitamin C exerted anti-wrinkle effect and enhanced collagen growth effect, as well as whitened skin by melanin decomposition.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the claim-designated ingredient for systemic administration in the making of the claimed method of treatment because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third

composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). Thus, at the time the invention was one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the claim-designated process step for the systemic administration of oral vitamin C as taught by Naito to the method of inhibiting the formation of unwanted skin pigmentation comprising the topical application to skin of a flavanoid and vitamin E as taught by Perrier because the claimed invention is no more than the combining of well known ingredients used in well known methods for increasing the ratio of light melanin to dark melanin in the skin of a mammal when administered by specific routes of administration.

Therefore, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 8 and 17, as amended; and newly added Claim 18 are/is rejected under 35 U.S.C. 103(a) as being unpatentable over Perrier et al. (A*) and Naito et al. (N) in view of Takagaki et al. (O), and further in light of Shrikhande et al. (B**). Newly applied as necessitated by amendment.

Applicant's claimed invention of Claims 8 and 17 was set forth above. Applicant further claims the method according to claim 8 wherein the flavanoid is an extract of the bark of the French maritime pine.

The combined teachings of Perrier and Naito made evident by Shrikhande as set forth above, teach the claimed invention except for wherein the flavanoid is an extract of the bark of the French maritime pine. However, modification of the method taught by the combined references as disclosed by Applicant would have been obvious to the artisan of ordinary skill because at the time of the invention Takagaki taught an extract of the bark of the French maritime pine containing proanthocyanidins and catechins exerting anti-tyrosinase activity; and, a method of use thereof comprising topical application of the pine bark extract to the skin of a mammal to not only whiten skin but also to inhibit collagenase. Since the pine bark extract of Takagaki was shown to be useful in the making of topical skin preparations for whitening skin and softening skin by inhibition of tyrosinase and collagenase, one of ordinary skill in the art would have had a reasonable expectation that the addition of the composition taught by Takagaki to the vitamin E/flavanoid-containing composition for topical application to the skin used in the method of whitening skin taught by the combined teachings of Perrier and Naito, would be a success. This reasonable expectation of success would have motivated the artisan of ordinary skill to make the modification to provide the instantly claimed invention, especially given that the combined teachings of Perrier and Naito taught that taught that topical administration of compositions comprising flavanoids in conjunction with systemic oral administration of vitamin C was useful in methods of skin lightening and/or

skin depigmenting, and enhancing collagen growth resulting in anti-wrinkle effect in skin.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the claim-designated ingredient for systemic administration in the making of the claimed method of treatment because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Therefore, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

**This reference is cited merely to relay an intrinsic property and is not used herein on the basis for rejection *per se*.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELE FLOOD whose telephone number is (571)272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele Flood
Primary Examiner
Art Unit 1655

MCF
November 21, 2009

/Michele Flood/
Primary Examiner, Art Unit 1655